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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/297,981	05/10/99	MEHEUS	L	INNS011/KAM

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EXAMINER	
ZEMAN, R	
ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/297,981	Meheus et al.
Examiner	**Art Unit**
Robert A. Zeman	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 10, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3, 5, and 19-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 5, and 19-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The amendment filed 3-10-2001 is acknowledged. Claims 4,6 and 14-15 have been canceled. Claims 1-3, 5 and 19-22 have been amended. Claim 24 has been added. Therefore, claims 1-3, 5, and 19-24 are pending and currently being examined.

Objections Withdrawn

Specification

The objection to the disclosure for not having the description of Drawings is not labeled as such is withdrawn in light of the amendment thereto.

Claim Objections

The objection to claims 1-3 and 5 for failing to be introduced by an article is withdrawn in light of the amendment thereto

New Claim Objections

Claim 2 is objected to because of the following informalities: Said claim refers to Table 4 as a limitation of the claims. Appropriate correction is required.

Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides comprising the amino acid sequence of SEQ ID NO:1-15, does not reasonably provide enablement for "analogues of said peptides comprising conservative amino acid substitutions" is maintained for reasons of record.

Applicant argues:

1. The definitions outlined in the specification clearly enable an artisan to make the claimed invention.

2. The term "analog" includes any protein or peptide having an amino acid sequence substantially identical to a claimed sequence where one or more residues have been conservatively substituted with a biologically equivalent residue.

3. Claim 1 limits analogs to peptides which have at least one arginine residue which is mono- or di-methylated and react with antibodies present in patients with systemic lupus erythmatosus, mononucleosis, or cancers associated with Epstein-Barr virus infection.

Applicant's arguments have been fully considered and are deemed to be non-persuasive.

As outlined in the previous Office action, the specification fails to define what is meant by an "analog". The specification is silent on what percentage of divergence is required to be considered an analog and at what point does an "analog" become totally unrelated. Applicant fails to disclose what biochemical/immunological properties must be present in order for a peptide to be

considered an "analog". The limitations outlined by Applicant in his argument fails to address these shortcomings. The limitation that said peptides react with antibodies in patients with various maladies fails to address the innumerable different antibody profiles that exist among the described pool of patients. Additionally, there is no requirement that a given peptide react with an antibody associated with one of the recited diseases. With regard to the limitation that all peptides with at least 1 amino acid substituted are considered analogs: Substitution of a single amino acid, conservative or otherwise, can lead to a biochemical/immunological major change in the peptide. To say that it merely, state that it has the limitation that it must react with **an** antibody from one of the recited patients does not enable one of skill in the art to make and use the claimed invention. The substitution could allow the peptide to react with an antibody that isn't even remotely associated with a disease.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The rejection of claims 1-2, 19-20 and 23-24 under 35 U.S.C. 102(e) as being anticipated by Heipe et al. (U.S. Patent 5,945,105) is maintained for reasons of record.

Applicant argues that since Hiepe et al. does not disclose the use of peptides containing methylated arginine residues said reference cannot anticipate the instant claims.

Applicant's argument has been fully considered and deemed to be non-persuasive.

As outlined in the previous Office Action Hiepe et al. discloses peptides of 35 to 45 amino acids comprising SEQ ID NO:1 and SEQ ID NO:4 as well as kits containing said peptides bound to a solid support.(see column 4, lines 59-67 to column 6, lines 51) and mutants and **variants** thereof. Since peptides with differing methylation patterns would be considered a variants of the disclosed peptides, Hiepe et al. anticipates all the limitations of the claimed invention.

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for kits comprising peptides for the detection of anti-Sm-D1 antibodies, does not reasonably provide enablement for diagnostic kits for detection of autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to use the invention commensurate in scope with these claims. The specification provides guidance for the making of peptides that contain an immunoepitope of Sm-D1. The specification further demonstrates the use of said peptides to detect antibodies against Sm-D1. However, the specification fails to provide any correlation between the presence of anti-Sm-D1 antibodies and the ability to diagnose any autoimmune diseases. Moreover, the specification does not provide guidance on how one would differentiate between the various autoimmune diseases. One of skill in the art would not be able to correlate a given antibody titer with a specific disease.

Claim Rejections Withdrawn

35 USC § 112

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the phrases "symmetrical dimethyl arginine" and "asymmetrical dimethyl arginine". and the use of parentheses is withdrawn in light of the amendment thereto.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, for use of the phrases "such as" and "can be implicated" is withdrawn in light of the amendment thereto.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the phrases "attached to specific locations" and "range of peptides" is withdrawn in light of the amendment thereto.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by use of the phrase "in the form of parallel lines" is withdrawn in light of the amendment thereto.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph, for being rendered vague and indefinite by the use of the term "certain peptides" is withdrawn in light of the amendment thereto.

35 USC § 103

The rejection of claims 1-3, 5, 19-21 and 23 under 35 U.S.C. 103(a) as being unpatentable over Rokeach et al. (PNAS Vol. 85 pages 4832-4836) in view of Rawal et al. (Biochimica et Biophysica Acta Vol. 1248 (1995) pages 11-18, IDS-10) is withdrawn. Applicant's arguments have been fully considered and are deemed to be persuasive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

May 21, 2001